REMARKS

Claims 10-16 currently appear in this application. The Office Action of August 7, 2008, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicant respectfully requests favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

Claim Amendments

Claims 1-9 are now cancelled. Claim 12 has been amended to recite suppressing the formation of isomers. Support for this amendment can be found in the specification as filed at paragraphs 0001, 0007 and 0027. New claims 14-16 are supported by paragraph 0005.

Rejections under 35 U.S.C. 112

Claims 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The

Examiner alleges that there is no formulation of trans-ED-71 in the specification.

This rejection is respectfully traversed. The subject matter of claim 12 is clearly described in the specification as filed at paragraphs 0013 and 10014. The subject matter of claim 13 is clearly described in the specification as filed at paragraph 0036.

The specification at paragraphs 0013 and 0014 describes the degradation products of ED-71, namely the degradation products of (5Z,7E)-(1R,2R,3R)-2-(3-hydroxypropoxy)-9,10-secocholesta-5,7,10(19)-triene-1,3,25-triol.

Paragraph 0036 reads as follows:

> In a state in which the generation of the degradation product of ED-71 is suppressed, the amounts of each of the tachysterol and trans forms generated after 12-month storage at room temperature under shading is preferably 1% or less, more preferably 0.3% or less, and particularly preferably 0.1% or less.

Claims 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which application regards as the invention. Claims 10 and 11 are said to be duplicates.

This rejection is respectfully traversed. Claim 11 has been amended so that it depends from claim 10.

Art Rejections

Claims 1 and 5-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al., WO 03/047595, Miyamoto et al., US 4,666,634 and Miyamoto et al., *Chem. Pharm. Bull.* **41(6)** 111-113, 1993.

This rejection is respectfully traversed.

Claims 1 and 5-9 have been cancelled, so this rejection is moot with respect to claims 1 and 5-9.

Claim 12 recites a method for suppressing the generation of the tachysterol and/or trans form of ED-71, which are isomers of ED-71. Referring to the structural formulas depicted in paragraphs 0008 and 0010 of the present specification, it is clear that the tachysterol and the trans forms are geometric isomers of ED-71.

In contrast thereto, it is apparent that Chen teaches the sue of antioxidants such as ascorbyl palmitate, BHA, BHT and tocopherols, which are mentioned in paragraph 0046, for suppressing oxidation of an active vitamin D compound to improve storage stability of a pharmaceutical composition containing an active vitamin D compound. This view is supported by the descriptions of paragraph 007 of Chen, that calcitriol is light-sensitive and is especially prone to oxidation. Paragraph 0008 of Chen states that a need exists in the art for a pharmaceutical composition comprising an active vitamin D compound that remains stable over a prolonged period of time, even at elevated

temperatures. Therefore, one skilled in the art would understand that Chen describes suppression of the generation of an oxidation product by adding an antioxidant.

It should be noted that Chen is completely silent with respect to degradation of a pharmaceutical composition containing an active vitamin D compound caused by isomerization of the active vitamin D compound ore the isomers formed by the isomerization.

Miyamoto in the '634 patent and in the *Chem. Pharm. Bull*, neither discloses nor suggests isomerization of ED-71 nor of any isomers of ED-71. therefore, neither Miyamoto reference adds anything to the disclosure of Chen to render the present claims obvious.

Since neither Chen nor either Miyamoto reference teaches the isomerization of ED-71 or the isomers of ED-71, there is no motivation for one skilled in the art to combine the teachings of Chen and Miyamoto to arrive at the suppression of

generation of isomers such as tachysterol and/or the trans form of ED-71 by adding an antioxidant.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

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